

REMARKS

I. Introduction

Claims 1-20 are pending in this application, of which claim 1 is independent. Claims 1-20 have been rejected. Claims 2-3, and 6 are cancelled herein without prejudice. Claim 1 is amended herein. New claim 21 has been added. Support for the amendments may be found in the specification as filed, and specifically in paragraph 48 of the specification.

II. Claim Rejections Under 35 U.S.C. § 112

A. 35 U.S.C. §112, First Paragraph

Claims 1 – 20 have been rejected under 35 U.S.C. § 112, first paragraph. The Office Action indicates that the claimed subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. According to the Office Action, the claimed "simultaneously contacting a C5 to C7 polyol with a protein contained in a spotting solution or being present on an array" is not supported in the application as filed. In response, Applicant has deleted the word "simultaneously". Applicant submits that any grounds for this rejection have been eliminated, and therefore, requests its withdrawal.

B. 35 U.S.C. §112, Second Paragraph

Claims 1 – 20 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. According to the Office Action, recitation of "contacting a C5 to C7 polyol simultaneously with a protein contained in a spotting solution or being present on an array" is confusing and "[s]tep c) is unclear as to the step of allowing covalent fixation of the proteins on the surface of the support." The Office Action further states that "the inconsistent used of terminologies e.g., 'analyte-specific regions', 'a selected capture protein' in the preamble and 'protein' in the body provides for confusion" and "[t]he term 'analyte-*specific* regions', in the context of the claim, is indefinite as to the measure or basis by which specificity to the analyte is determined in the absence of any kind or structure of the analyte or capture protein."

Applicant addresses this rejection by implementing several amendments in claim 1. As noted above, Applicant removes the word "simultaneously" from claim 1, step (a). Applicant further deletes step (c) ("allowing covalent fixation of the proteins on the surface of the support") and amends step (b) to recite "depositing the spotting solution on one of the discrete analyte-specific regions of the surface of a nonporous solid support resulting in covalent binding of the capture proteins to the support".

Regarding the Examiner's assertion that the phrase "analyte-specific regions" is indefinite, this phrase is clearly defined in paragraphs [0018] and [0023] of the specification, as a spot on the solid support represented by a discrete region on the support spaced apart from another location and bearing a capture protein.

Applicant believes the aforementioned amendments and remarks fully address the rejections under 35 U.S.C. § 112, and therefore respectfully request their removal.

III. Claim Rejections Under 35 U.S.C. § 102

Claims 1 – 3, 5 and 8 – 12 have been rejected under 35 U.S.C. section § 102(e) as being anticipated by Stillman et al. (U.S. patent application no. 20030175827).

Stillman et al., (D3; US 200310175827) discloses a method for the preparation of a stable thin film dried protein composition on an inert surface of e.g. a solid support (surface having a protein denaturing capability, cf. claim 1). A thin film of a protein containing solution is applied to the surface of a solid support together with a saccharide, such as xylitol or mannitol, for stabilizing the protein during drying.

Stillman et al. fails to teach covalent binding of the capture proteins on the support, as is recited in the currently amended claim 1. The Examiner's comment that Stillman inherently teaches covalent bonding, is noted. Applicant points out that the courts have set very stringent requirements to establish inherency, and Applicant submits that Stillman does not meet those requirements.

Applicant respectfully reminds the Examiner that inherency of any but the most obvious sort must be based on extrinsic evidence. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

Applicant respectfully finds no disclosure in Stillman to substantiate such an inherency finding. Applicant is unaware of a scientific reason why covalent bonding would covalently link to Stillman et al.'s support, because Stillman et al. neither teaches an active group either on the support nor on the protein for spontaneous covalent binding. In addition, Stillman et al. does not teach a coupling agent present in the solution. Proteins dried on supports do not inherently link to the support, i.e. albumin dried on a glass support does not covalently link to the support. If the Examiner is aware of disclosures that would indicate that all proteins dried on all supports inherently covalently bond to the support, Applicant kindly requests the references be cited for the Applicant's review. Without being aware of any such references, Applicant maintains that Stillman et al. does not teach covalent binding as required by claim 1 step (b) of the present application.

Further, in the example of Stillman et al. (D3 [0020]), the proteins are spotted on glass that is coated with microporous material, such as cellulose nitrate ester. In contrast, claim 1 has been amended to recite "a nonporous solid support". Support for this amendment may be found in paragraph [0048] of the specification as published.

The requirements of the present application's claim 1 for a nonporous support and covalent binding offer particular advantages over Stillman's et al's disclosure. For instance, covalent binding allows a user to wash the support after the protein has dried but before running a binding assay, to remove the polyols and expose the proteins, without having as much concern of washing of the proteins, as would be necessitated by Stillman's model. The claimed embodiments allow the amount of immobilized protein to be better controlled, because the

covalent link is resistant to washing. *See* paragraphs [0062], [0063], [0084], [0095], and [0101] of the present specification as published. Further, the nonporous surface of the claimed embodiments permit the reactive sites of the immobilized proteins to be directly available for reacting with target proteins present in solution. In contrast, the immobilized proteins of Stillman et al., may be hidden in a complex network of pores, prohibiting the reactive sites of the proteins from reacting in the binding assay. Therefore, Stillman et al.'s binding assay would be more likely than the claimed embodiments to indicate less binding in the binding assay than the protein initially dried on the support may be capable of.

Moreover, it should also be noted that Stillman et al. discloses as the second step of its three step method: "to apply a thin film of the solution to a support having a surface for depositing, the surface having a protein denaturing capability" (cf. Stillman et al., section [0010] and claim 10). Hence, Stillman et al.'s method indicates that the procedure denatures the proteins prior to running the binding assays having classical antigen-antibody reactions (Stillman et al. [0023 and 0024]). Stillman et al.'s binding tests may not present an accurate reflection of the native proteins' binding ability if the proteins are said to be denatured by the support. In contrast, the teachings of the present disclosure prevent protein denaturation by providing a combination of a support, polyol and spotting solution to maintain the proteins tertiary structure, even after covalent binding to the support, so that the binding assay will be an accurate reflection of the native protein's binding abilities.

Accordingly, Stillman et al. does not disclose all of the features of claims 1 – 3, 5 and 8 – 12. Applicant respectfully requests that the 35 U.S.C. §102 rejection be withdrawn.

IV. Claim Rejections Under 35 U.S.C. § 103

Claims 1 – 15 and 18 – 20 have been rejected under 35 U.S.C. section 103(a) as being unpatentable over any one of Decker (GB 2,016,687A) or Devereaux (WO 93/07466) or Stillman et al. in view of either Guo (Faming Zhuanli Shenqing Gongkai) or Sandford (U.S. patent application no. 20030134294) and Schultz et al. (U.S. patent application no.

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20040198637). Claims 16 and 17 were rejected under 35 U.S.C. section 103(a) as being unpatentable over any one of Decker or Devereaux or Stillman et al. in view of either Guo or Sandford and Schultz, and further in view of Moreadith (U.S. patent no. 6,632,934).

Applicant notes that Examiner indicates Schultz teaches that a protein can be covalently or non-covalently linked to an array in a manner that preserves its function. *See* Office Action pages 9-10 quoting Schultz [0048]. Even if the Examiner's observation is correct, Applicant respectfully notes that Schultz was filed after the filing date of the present application; the present application was filed on November 25, 2003, and then Schultz was filed on December 22, 2003. Hence, Schultz is an improper reference under 35 U.S.C. §103. Without Schultz, the combination of references fails to teach or suggest all of the elements of the claimed embodiments.

Furthermore, the Examiner has improperly relied on the English language abstract of Guo without providing a translation as required by USPTO procedure. The Applicant respectfully requests the Examiner provide an English language translation of the Guo publication, so that the Applicant may effectively respond to the Office Action.

The Board of Patent Appeals and Interferences established the proper procedure for the citation of foreign language documents in *Ex parte Jones*:

In the event a reference is in a foreign language, if the applicant does not wish to expend resources to obtain a translation, the applicant may wish to request the examiner to supply a translation. If a translation is not supplied by the examiner, the applicant may wish to consider seeking supervisory relief by way of a petition (37 CFR § 1.181) to have the examiner directed to obtain and supply a translation.

Ex parte Jones, 62 U.S.P.Q.2d 1206, 1208 – 1209 (2001). The rationale behind the *Ex parte Jones* rule:

In our [the board's] view, obtaining translations is the responsibility of the examiner. A review by the examiner and applicant of translations of the prior art relied upon in support of the examiner's rejection may supply additional relevant evidence as to whether there is a legally sufficient reason, suggestion, teaching or motivation to combine the teachings of the five technical journal articles. Moreover, an evaluation of translations may eliminate the need for an appeal.

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Id. at 1209. Please note that, although Jones particularly involved a rejection under 35 U.S.C. § 103, the Board did not limit its decision to prior art cited in obviousness rejections.

The requirement that the Examiner provide an English translation when an abstract of a foreign-language document has been relied upon in a rejection has been incorporated in the MPEP at section 706.02 Part II:

When an abstract is used to support a rejection, the evidence relied upon is the facts contained in the abstract, not additional facts that may be contained in the underlying full text document. Citation of and reliance upon an abstract without citation of and reliance upon the underlying scientific document is generally inappropriate where both the abstract and the underlying document are prior art. See *Ex parte Jones*, 62 USPQ2d 1206, 1208 (Bd. Pat. App. & Inter. 2001) (unpublished). To determine whether both the abstract and the underlying document are prior art, a copy of the underlying document must be obtained and analyzed. If the document is in a language other than English and the examiner seeks to rely on that document, a translation must be obtained so that the record is clear as to the precise facts the examiner is relying upon in support of the rejection. [Emphasis added]

Applicant respectfully requests the Examiner provide an English translation of the alleged prior art reference. Applicants are hindered in their ability to respond to the Office Action, because references have been made to the abstract of a foreign-language patent. The Applicant makes no admission that the cited foreign language document constitutes prior art. If the Examiner does not provide English translations as required by *Ex parte Jones*, then the Applicant respectfully requests the Examiner withdraw the rejections of the claims over Guo on this basis, and allow all pending claims.

In response to the remaining references, Decker et al. (D1, GB 2016687) neither mentions a protein deposition on discrete regions of the solid support nor that the proteins are covalently attached to the support. Additionally, Decker et al. fails to teach the order of method steps, i.e. Decker et al. mentions a stabilization step subsequent a coating step with protein (cf. Decker et al. p.2, 1. 12 to 15). In contrast, new claim 21 discloses contacting of the polyol and protein with the solid support in the same step.

Like Decker et al., Devereaux et al., (D2, WO 93/07466) does not mention a protein deposition on discrete regions of the solid support. Further, Devereaux does not disclose contacting of polyols and capture probes with the solid support.

Sandford (D5, US 2003/0134294 or WO 03/050234) is introduced by the Examiner to provide motivation to use a borate buffer in the solution of e.g. Stillman. Sandford does not disclose, as is recited in new claim 21, contacting a protein and a linear polyol selected from the group consisting of mannitol, maltitol and sorbitol, with the support in a single step. Sanford further does not specify drying of the spotting solution. Additionally, Sandford does not mention a protein deposition on discrete regions of the support.

Moreadith (D6, US 6,632,934) neither mentions protein arrays nor specifies the usage of linear polyols selected from the group consisting of mannitol, maltitol and sorbitol for stabilizing arrays.

Additionally, claims 16 and 17 are rejected under 35 U.S.C. §103(a) as being unpatentable over any one of Decker or Devereaux or Stillman in view of either Guo and Schultz as applied to claims 1-15 and 18-20 above, and further in view of Moreadith. Applicant reasserts the arguments presented above, particularly that Schultz and Guo are improper references.

The documents together do not teach or suggest the elements of currently amended claim 1. Furthermore, the Examiner improperly relies on Schultz and Guo to teach elements of the rejected claim not taught or suggested by Decker, Devereaux, Stillman, or Sandford. Accordingly, it would not have been obvious to one having ordinary skill in the art at the time the invention was made to combine the above mentioned references. In view thereof, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. § 103 rejections.

V. Conclusion

Applicant respectfully requests entry of the foregoing amendments and remarks and reconsideration and withdrawal of all rejections. It is respectfully submitted that this application with claims 1-20 is in condition for allowance. If there are any remaining issues or the Examiner


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believes that a telephone conversation with the Applicant's attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at the telephone number shown below.

The Commissioner for Patents and Trademarks is hereby authorized to charge the two month extension of time fee, and is further authorized to charge any other deficiency in any fees or credit any overpayment in any fees accumulated during prosecution of this application to Deposit Account No. 50-0951.

Respectfully submitted,
AKERMAN SENTERFITT

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